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### REMARKS

The present response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

### Status of Claims

Claims 1-19 are pending in the application. Claims 1-19 have been rejected. Claims 1 and 18 have been amended. Claim 19 has been cancelled.

Applicants respectfully assert that the amendments to the claims add no new matter.

### CLAIM REJECTIONS

#### 35 U.S.C. § 112 Rejections

In the Office Action, the Examiner rejected claims 1-19 under 35 U.S.C. § 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claims 1 and 18 to recite "A method of treating a patient in need of increased vagal tone, comprising the step of delivering to said patient's cardiac autonomic structures a nucleic acid molecule encoding nitric oxide synthase which, when expressed, increases nitric oxide synthase levels", for which action, ample support exists under the Wands factors (*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir 1988)) in the specification.

Applicants therefore assert that claims 1 and 2 as amended, are proper under 35 USC 112 first paragraph. Each of claims 3-18 depend from claim 1 and therefore each of these claims are likewise proper under 35 USC 112 first paragraph; and request that these rejections be withdrawn. Claim 19 was cancelled, making its rejection moot.

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### 35 U.S.C. § 102 Rejections

In the Office Action, the Examiner rejected claims 1-3, 5 and 13-16 under 35 U.S.C. § 102(a), as being anticipated by Kishi et al, (2002, Hypertension 39:264-268). Applicants respectfully traverse this rejection in view of the remarks that follow.

In response, Applicants have amended claim 1 to recite: "A method of treating a patient in need of increased vagal tone, comprising the step of delivering to said patient's cardiac autonomic structures a nucleic acid molecule encoding nitric oxide synthase which, when expressed, increases nitric oxide synthase levels."

Kishi et al., discloses targeted delivery of adenoviral vectors encoding endothelial NOS (AdcNOS) into rostral ventrolateral medulla (RVLM), which contains sympathetic premotor neurons responsible for maintaining the tonic excitation of sympathetic preganglionic neurons involved in cardiovascular regulation to modulate sympathetic activity, requiring extensive brain surgery. Kishi et al., does not teach the delivery of a nucleotide encoding neuronal NOS (nNOS) to cardiac autonomic structures thereby increasing NOS expression in intracardiac ganglia.

In order to successfully assert a prima facie case of anticipation, the Examiner must provide a single prior art document that includes every element and limitation of the claim or claims being rejected. Since Kishi et al., does not teach every element of Applicants' independent claim 1, Kishi et al., does not anticipate these claims.

Applicants therefore assert that claims 1 and 2 as amended, are proper under 35 USC 102 (a). Each of claims 3, 5 and 13-16 depend from claim 1 and therefore each of these claims are likewise allowable under 35 USC 102 (a). Accordingly, Applicants respectfully request that the Examiner withdraw the rejections to claims 1-3, 5 and 13-16 under 35 U.S.C. § 102(a), as being anticipated by Kishi et al..

### 35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 6, 7, 9-11 and 13-19 under 35 U.S.C. § 103(a), as being unpatentable over Kishi et al, (2002, Hypertension 39:264-268), as applied to claims 1-3, 5, 13-16.

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Applicants respectfully traverse the rejection of claims Kishi et al, (2002, Hypertension 39:264-268) under Yi-Fan et al (2002, Am J. Heart Giro, Physiol 282:H594-H601), Lonnerberg et al (1995, Proc.Natl Acad Sci USA 92: 4046-4050), Edelberg et al (2001, Heart 86.559-562).

Applicants respectfully traverse the rejection of claim 6 based on Kishi et al., in view of Yi-Fan et al (2002, Am J. Heart Giro, Physiol 282:H594-H601)

As discussed above, claim 1 as amended, is allowable over the prior art of record. Yi Fan et al., delivers nNOS to the paraventricular nucleus (PVN) of the hypothalamus, which do not cure the deficiencies of Kishi et al. Claim 6 depends from claim 1 and therefore includes all the limitations of that claim. Therefore, claim 6 is likewise allowable. Applicants thus request that the Examiner withdraw the rejection of claim 6, under 35 U.S.C. § 103 based on Kishi et al., in view of Yi-Fan et al (2002, Am J. Heart Giro, Physiol 282:H594-H601).

Applicants respectfully traverse the rejection of claim 9 and 18-19 based on Kishi et al., in view of Lonnerberg et al (1995, Proc.Natl Acad Sci USA 92: 4046-4050).

As discussed above, claim 1 as amended, is allowable over the prior art of record. Lonnerberg et al., teaches cholinergic specific promoter methods of construction and expression to several cholinergic regions of the central nervous system of transgenic mice; including basal forebrain, cortex, pons, and spinal cord, which do not cure the deficiencies of Kishi et al. Each of claims 9 and 18 depends from claim 1 and therefore includes all the limitations of that claim. Therefore, claims 9 and 18 are likewise allowable. Claim 19 was cancelled, making its rejection moot. Applicants thus request that the Examiner withdraw the rejection of claims 9 and 18, under 35 U.S.C. § 103 based on Kishi et al., in view of Lonnerberg et al (1995, Proc.Natl Acad Sci USA 92: 4046-4050).

Applicants respectfully traverse the rejection of claim 7, 10-11 and 13-16 based on Kishi et al., in view of Edelberg et al., (2001, Heart 86.559-562).

As discussed above, claim 1 as amended, is allowable over the prior art of record. Edelberg et al., teaches the injection of plasmids encoding the human  $\beta_2$  adrenergic receptor, which does not cure the deficiencies of Kishi et al. Each of claims 7, 10-11 and 13-16

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depends from claim 1 and therefore includes all the limitations of that claim. Therefore, claims 7, 10-11 and 13-16 are likewise allowable. Applicants thus request that the Examiner withdraw the rejection of claims 7, 10-11 and 13-16, under 35 U.S.C. § 103 based on Kishi et al., in view of Edelberg et al., (2001, Heart 86.559-562).

Applicants thus request that the Examiner withdraw the rejection of claims 6, 7, 9-11 and 13-18, under 35 U.S.C. § 103 based on Kishi et al, (2002, Hypertension 39:264-268), as applied to claims 1-3, 5, 13-16 in view of Yi Fan et al., (2002, Am J. Heart Giro, Physiol 282:H594-H601), Lonnerberg et al (1995, Proc.Natl Acad Sci USA 92: 4046-4050), Edelberg et al., (2001, Heart 86.559-562).

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Since the Examiner does not suggest that the Kishi et al, teaches or suggests all the elements of independent claim 1, and neither Yi Fan et al (2002, Am J. Heart Giro, Physiol 282:H594-H601), Lonnerberg et al (1995, Proc.Natl Acad Sci USA 92: 4046-4050), nor Edelberg et al (2001, Heart 86.559-562) cure these deficiencies; the Examiner fails to establish a prima facie showing that Kishi et al, Yi Fan et al (2002, Am J. Heart Giro, Physiol 282:H594-H601), Lonnerberg et al (1995, Proc.Natl Acad Sci USA 92: 4046-4050), or Edelberg et al (2001, Heart 86.559-562), alone or in combination, teach or suggest every feature of claim 1.

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### CONCLUSION

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

  
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